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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Lasse W. Mogensen et al.	:	
Serial No.: 10/687,568	:	Confirmation No.: 7139
Filed: October 15, 2003	:	Group Art Unit: 3767
For: INJECTOR DEVICE FOR PLACING A SUBCUTANEOUS INFUSION SET	:	Examiner: Elizabeth Moulton

REPLY BRIEF

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Sir:

In accordance with 37 C.F.R. § 41.41, Appellants file this Reply Brief within two months from the date of the Examiner's Answer of November 12, 2009, regarding the above-mentioned patent application.

A. STATUS OF THE CLAIMS

A correct statement of the status of the claims is as follows and should replace the statement made in Section III of Appellants' Appeal Brief filed on August 5, 2009:

Claims 55, 57, 66, 70, 71 and 73, all claims presented, are rejected and appealed. Claims 1-39 and 44-49 are canceled. Claims 40-43, 50-54, 56, 61-65, 67 and 68 are allowed.[1] Claims 59, 60, 69 and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.[2]

B. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Please replace the grounds of rejection at Section VI of Appellants' Appeal Brief with the following two grounds of rejection presented for review:

1) the rejection of claims 55, 57, 66, 70, 71 and 73 under 35 U.S.C. § 102(b) as being anticipated by Miskinyar, U.S. Patent No. 4,894,054[3]; and

2) the rejection of claim 58 under 35 U.S.C. § 103(b) as being obvious in view of Miskinyar and Teeple, Jr., U.S. Patent No. 5,807,316.[4]

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[1] The rejections of claims 56 and 61-64 have been withdrawn and the claims have been allowed per pages 2 and 3 of the Examiner's Answer.

[2] The rejections of claims 59, 60, 69 and 72 have been withdrawn and the claims have been indicated to contain allowable subject matter per pages 2 and 3 of the Examiner's Answer.

[3] It is noted that the "Evidence Relied Upon" section at page 3 of the Examiner's Answer lists U.S. Patent No. 5,527,287 to Miskinyar while paragraph 1 of section (9) at page 3 of the Examiner's Answer presents a rejection based on U.S. Patent No. 4,894,054 to Miskinyar. Since the Office Action of April 22, 2009 relied on the '054 patent to reject the claims, Appellants will treat the reference to the '287 patent in the "Evidence Relied Upon" section as being made in error.

[4] It is noted that the Examiner's Answer does not include the rejection of claims 55-57, 60-64, 66 and 69-73 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,293,925 to Safabash et al. as presented in the Office Action of April 22, 2009. Accordingly, Appellants will treat the rejection as being withdrawn.

C. ARGUMENT

(1) Miskinyar does not teach a "deformable" housing.

At page 5 in section (10)1.(a.i.) of the Examiner's Answer, the Examiner asserts "the housing (as a whole) changes shape or deforms." The assertion has no merit.

As described in Appellants' specification at paragraph 43, "release of the plunger 30 may be caused by pressing manually on diametrically opposed outside areas of the device housing 28 to deform the housing 28 and thereby effect release of the trigger arms 38." Such pressing causes the shape of the housing 28 to change. Such a definition is supported by the dictionary (Merriam-Webster's Collegiate Dictionary, Tenth Edition, 1998, p. 303), wherein the term "deformable" is defined to mean "to alter the shape of by stress" or "to become misshapen or changed in shape" or "distort." The plain meaning of the term "deform" is very different from translationally moving a button from one position to another where the button itself does not change shape. Clearly, the button 33 of Miskinyar that moves up and down as asserted by the Examiner does not result in a change in shape or form of the button 33 of Miskinyar in a manner as required by the housing recited in claims 72, 78, 86 and 87. Miskinyar clearly does not teach or suggest that any part of the device is "deformable."

At page 5 in section (10)1.(a.iii.) of the Examiner's Answer, the Examiner asserts that the sides or the top of the button, or any surface of the button of Miskinyar is a manual engagement area and that the button may be pushed at both sides to deploy the plunger. This assertion is also incorrect. Appellants' claim 73 recites that the housing includes a pair of manual engagement areas, the manual engagement areas are pressed radially inwardly in the second geometrical configuration. Claim 73 depends directly from claim 55 and as discussed above, Miskinyar does not teach or suggest that any part of the device is "deformable." In addition, the button 33 of Miskinyar supports, on its undersurface, a knife 42 with a circular blade and cutting edges 66 that is aligned with plastic ring 56 so that it will

puncture the plastic ring and discharge the pressured air into the ampoule chamber to inject the medication into the patient. (*See* Col. 3, lines 30-42.) In other words, the button 33 must be pressed downward in the direction of the patient so that the knife 42 can release the air and cause injection of the medication. Pressing radially inwardly on the button 33 of Miskinyar does not deform the button 33 and does not cause the button 33 to move downward toward the patient as required for operation of the Miskinyar device. Miskinyar clearly does not teach or suggest that the housing includes a pair of manual engagement areas or that the manual engagement areas are pressed radially inwardly in the second geometrical configuration as recited in claim 73.

(2) "Capable of being removed" does not include cutting the needle.

At pages 5-6 in section (10)1.(bi) of the Examiner's Answer, the Examiner asserts there is nothing in the claims about the needle or cannula remaining in the patient or even being removable once inside the patient." The Examiner is correct that the claims are silent about such matters. As pointed out at pages 29-31 of Appellants' Appeal Brief, there is no suggestion in Miskinyar to cut off its hypodermic needle 22.

In fact, Miskinyar teaches disposing the device after use and using the protective cover 38 for **totally enclosing** the needle 22. (Col. 4, lines 33-37 and Col. 6, lines 45-48.) In addition, a special advantage of the invention according to Miskinyar is that the device is very safe, such that there is no possibility of passing a contagious or infectious disease such as AIDS or other HIV viruses. (Col. 8, lines 8-11.) One of skill in the medical arts would clearly interpret the term "positioned removably from and within said device housing" as recited in claim 66, to NOT include a needle that is cut off.

Yet, that is what the Examiner suggests when she modifies Miskinyar in an effort to anticipate the claimed infusion set having a housing and cannula. Nowhere does Miskinyar teach that its needle is intended to be cut from the syringe. Nonetheless, the Examiner alters the intended purpose of the needle 22 of

Miskinyar "by cutting" it from the housing. According to the Examiner, since the needle 22 can be cut, it is capable of being removed and thus is a removable part of the infusion set. The Examiner cannot cite to any case where a reference had been modified from its intended purpose in order to prove anticipation. Miskinyar clearly fails to teach or suggest an infusion set that is removable from the plunger.

(3) The combination of Miskinyar and Teeple Jr. do not teach a manually deformable housing or indicia relating to shelf life of the assembly.

At page 6 in section B of the Examiner's Answer, the Examiner refers to the discussion of the button 33 of Miskinyar that moves up and down, which makes it manually deformable. As discussed above in section C(1) of Appellants' Reply Brief, this assertion is incorrect. In addition, Teeple Jr. is directed to the mixing and delivery of anesthesia and not to an injector device assembly. Teeple Jr. also does not teach or suggest a manually deformable housing and cannot make up the deficiencies of Miskinyar. Appellants' claim 58 recites a housing that is manually deformable from a first geometrical housing configuration to a second geometrical housing configuration. Miskinyar and Teeple, Jr., together and individually, clearly do not teach or suggest that any part of the device is "deformable."

At page 6 in section B of the Examiner's Answer, the Examiner also asserts that the shelf life in the claims is not limited to the sterile shelf life of the device and that it would be obvious to list the shelf life of the drug so that an expired or degraded drug is not delivered to the patient. While it is true that the shelf life in claim 58 is not limited to the device, the Examiner's assertion ignores the recitation in claim 58 requiring "indicia relating to the shelf life **of the assembly**." The Examiner does not explain how the bar code and bar code reader for tracking expired anesthetic drugs can be used for indicia relating to the shelf life of the injector device assembly.

D. CONCLUSION

For at least these reasons and all other reasons set forth above and in the Appellants' opening brief, the rejections of claims 55, 57, 58, 66, 70, 71 and 73 as well as the objection to claims 59, 60, 69 and 72, should be **REVERSED** and all of those claims allowed.

Respectfully submitted,

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